ZyVersa Therapeutics CEO Issues Mid-year Shareholder Letter Highlighting Recent Corporate Developments and R&D Progress

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WESTON, Fla., July 21, 2025 (GLOBE NEWSWIRE) -- ZyVersa Therapeutics, Inc. (Nasdaq: ZVSA; "ZyVersa"), a clinical stage specialty biopharmaceutical company developing first-in-class drugs for treatment of patients with renal and inflammatory diseases who have unmet medical needs, announces that Stephen C. Glover, Co-Founder, Chairman, Chief Executive Officer, and President, has issued a mid-year Shareholder Letter to update investors on recent corporate developments and to highlight near-term value-building R&D milestones for second half of 2025. The full text of the letter follows.

A MESSAGE FROM OUR CHIEF EXECUTIVE OFFICER

Dear Shareholders:

Over my 40-year career, I've seen the full arc of biotech—celebrated successes and weathered setbacks. Today's biotech environment ranks among the most challenging we've faced: capital markets remain tight, sector valuations are compressed, major exchanges are underperforming, and investor sentiment is cautious. Yet history teaches us that it's in these moments—when others pull back—that focused, disciplined companies with sound science and strong leadership can chart a breakthrough course.

At ZyVersa, we believe we are exceptionally positioned to do just that. Our pipeline is advancing. Our science is differentiated. Our mission—to deliver transformative therapies for patients with serious unmet needs—has never been more urgent. But to realize this potential, your continued support is essential.

We remain deeply committed to executing with discipline and urgency. In a market that rewards resilience, ZyVersa is staying the course—with focus, strategic clarity, and resolve. Together, we can build long-term value for patients, the healthcare system, and our shareholders.

I am pleased to announce that in Q2-2025, we closed two financing transactions providing access to $12 million in capital to advance our R&D initiatives. On July 8, 2025, we closed a $2M warrant inducement transaction from a current investor, and on June 25, 2025, we closed a Share Purchase Agreement for up to $10 Million in Partnership with Williamsburg Venture Holdings. This increased capital supports advancement of our key development programs targeting kidney and inflammatory diseases to value-building inflection points over the next several months.

Cholesterol Efflux Mediator™ VAR 200 for Kidney Diseases

VAR 200 uniquely targets a neglected pathway leading to development and progression of kidney diseases—accumulation of excess lipids in the kidneys' filtration system that causes kidney damage, inflammation, and fibrosis leading to kidney dysfunction. Our lead indication for VAR 200 is rare kidney disease, focal segmental glomerulosclerosis ("FSGS"), with potential indication expansion into rare kidney disease, Alport syndrome, and diabetic kidney disease (DKD). Prior to initiating a Phase 2a trial in patients with FSGS, we initiated a small open-label Phase 2a trial in patients with DKD mid-June 2025, in which we expect to obtain patient proof-of-concept data more quickly than in an FSGS trial. This will enable assessment of drug effects as patients proceed through treatment and will provide insights for developing a larger Phase 2a/b protocol in patients with FSGS. Preliminary data are expected to be reported in Q4-2025, with final results anticipated in H1-2026.

Based on the unique mechanism of action of VAR 200, we provided drug and regulatory support under FDA-authorized *Emergency Compassionate Use* to treat a patient at the University of Miami Miller School of Medicine who has ApoCII amyloidosis, a very rare disease which mainly affects the kidney. *Emergency Compassionate Use* was authorized because the patient has no other effective treatment options to treat her serious condition.

There is a tremendous unmet need for effective renal drug therapies and innovation in this space is not just a medical imperative, it's a market opportunity with transformative potential.

- Kidney disease, which affects over 850 million people globally, has limited treatment options and none modify the disease which continues to progress, ultimately to kidney failure requiring dialysis or transplant for survival.
- Two million patients worldwide are living with kidney failure, which negatively impacts quality of life and increases mortality risk.
- In the US, kidney disease consumes around 25% of Medicare spending—over $130 billion annually.

The good news is that regulators recognize that kidney disease is one of the most pressing global health challenges, and they are taking steps to reduce drug development barriers to motivate investment in innovation.

- The FDA and EMA are actively supporting innovation in kidney disease with accelerated pathways for rare and serious diseases.
- Initiatives like PARASOL are expected to shorten the time and reduce the number of patients required for clinical trials, while enabling greater interaction with regulatory authorities.

Investors are increasingly recognizing that first-in-class kidney drug therapies, like SGLT2 inhibitors, have blockbuster potential, and can build franchises—not just single assets.

Inflammasome ASC Inhibitor IC 100 for Inflammatory Diseases

IC 100 is the only inflammasome inhibitor targeting the inflammasome ASC component to uniquely block not only initiation of the inflammatory cascade, but also the spread and perpetuation of inflammation that damages tissues and organs leading to their dysfunction and chronic diseases. Our lead indication for IC 100 is obesity with cardiometabolic comorbidities, with potential indication expansion into neurological diseases such as Parkinson's and Alzheimer's diseases. Plans are underway with the University of Miami Miller School of Medicine to initiate an IND-enabling preclinical study in a diet-induced obesity (DIO) animal model in Q3-2025.

Other IC 100 developments:

- Data published in April 2025 demonstrate that IC 100 reduces neurotoxic alpha-synuclein accumulation, a key contributor to neurodegeneration and Parkinson's disease progression (study funded by Michael J. Fox Foundation, MJFF).
- Invited request from MJFF to submit a second grant request to fund IND-enabling preclinical studies in Parkinson's disease.

Near-term Milestones

- VAR 200: Preliminary data for Phase 2a clinical trial in DKD, Q4-2025
- IC 100: Initiation of IND-enabling DIO preclinical study Q3-2025

We are happy to announce that on July 17, 2025, we began trading on the OTC Market to optimize company growth and build shareholder value. We are trading under the same ticker symbol, ZVSA.

In closing, we call on you, our shareholders, to:

- Support your investment with your belief that new innovative medicines make a difference for patients and society.
- Recognize the opportunity for long-term value creation as we execute in a market where disciplined, science-driven companies will emerge stronger.
- Stand with management and the Board as we make bold, necessary decisions to weather near-term pressures and drive toward key inflection points over the next six months.

The Bottom Line: In a cautious market, conviction matters. ZyVersa is committed to building breakthrough value in kidney and inflammatory diseases, grounded in rigorous science and strategic execution. We thank you for your continued trust and partnership. With your support, we can seize this moment—transforming patient outcomes while delivering long-term value for shareholders.

Sincerely,
Stephen C. Glover
Co-Founder, Chairman, Chief Executive Officer, and President
ZyVersa Therapeutics

ABOUT ZYVERSA THERAPEUTICS, INC.

ZyVersa (Nasdaq: ZVSA) is a clinical stage specialty biopharmaceutical company leveraging advanced, proprietary technologies to develop first-in-class drugs for patients with renal and inflammatory diseases who have significant unmet medical needs. The Company is currently advancing a therapeutic development pipeline with multiple programs built around its two proprietary technologies – Cholesterol Efflux Mediator™ VAR 200 for treatment of kidney diseases, and Inflammasome ASC Inhibitor IC 100, targeting damaging inflammation associated with numerous CNS and peripheral inflammatory diseases. For more information, please visit www.zyversa.com.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

Certain statements contained in this press release regarding matters that are not historical facts, are forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995. These include statements regarding management's intentions, plans, beliefs, expectations, or forecasts for the future, and, therefore, you are cautioned not to place undue reliance on them. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. ZyVersa Therapeutics, Inc. ("ZyVersa") uses words such as "anticipates," "believes," "plans," "expects," "projects," "future," "intends," "may," "will," "should," "could," "estimates," "predicts," "potential," "continue," "guidance," and similar expressions to identify these forward-looking statements that are intended to be covered by the safe-harbor provisions. Such forward-looking statements are based on ZyVersa's expectations and involve risks and uncertainties; consequently, actual results may differ materially from those expressed or implied in the statements due to a number of factors, including ZyVersa's plans to develop and commercialize its product candidates, the timing of initiation of ZyVersa's planned preclinical and clinical trials; the timing of the availability of data from ZyVersa's preclinical and clinical trials; the timing of any planned investigational new drug application or new drug application; ZyVersa's plans to research, develop, and commercialize its current and future product candidates; the clinical utility, potential benefits and market acceptance of ZyVersa's product candidates; ZyVersa's commercialization, marketing and manufacturing capabilities and strategy; ZyVersa's ability to protect its intellectual property position; and ZyVersa's estimates regarding future revenue, expenses, capital requirements and need for additional financing.

New factors emerge from time-to-time, and it is not possible for ZyVersa to predict all such factors, nor can ZyVersa assess the impact of each such factor on the business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Forward-looking statements included in this press release are based on information available to ZyVersa as of the

date of this press release. ZyVersa disclaims any obligation to update such forward-looking statements to reflect events or circumstances after the date of this press release, except as required by applicable law.

This press release does not constitute an offer to sell, or the solicitation of an offer to buy, any securities.

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